UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456 Master File No. 01-12257-PBS Subcategory Case No. 06-11337 -PBS
THIS DOCUMENT RELATES TO:	)	
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., Civil Action No. 06-11337-PBS	)	Hon. Patti B. Saris Magistrate Judge Marianne B. Bowler

UNITED STATES' OPPOSITION TO ABBOTT LABORATORIES' MOTION *IN LIMINE* TO EXCLUDE CERTAIN OPINIONS PROFFERED BY PLAINTIFFS' EXPERT MARK G. DUGGAN, PH.D.

Abbott seeks to exclude at trial a good portion of the testimony of the United States' expert witness who calculated the difference between what the government reimbursed for certain Abbott drugs, and what the government would have reimbursed had the prices Abbott reported been reflective of the actual prices at which it transacted business. Abbott seeks this unwarranted relief, even though it is indisputable that it reported certain drug prices that bore no relationship to actual prices, causing significant harm to Medicare and Medicaid. The evidence uncovered through fact and expert discovery shows that Abbott's price-reporting was part of its scheme to game the reimbursement system purely for financial gain. There is no serious issue about Abbott's culpability for its fraudulent price-reporting (resulting in mega-spreads of 101 to 1,685 percent). The only real issue is arriving at a reasonable estimate of damages, which is exactly what the United States' expert did. Abbott's motion to exclude the reasonable and conservative estimate that the United States seeks to admit should be denied.

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INTRODUCTION

The United States retained Mark Duggan, Ph.D., to calculate a reasonable estimate of damages. Dr. Duggan is a Harvard-trained economist currently taking a one-year sabbatical from his tenured university position to be the Senior Economist for Health Care on President Obama's Council of Economic Advisors. Dr. Duggan has substantial experience applying econometric principles to empirical studies of nationwide Medicaid spending, exactly the type of expertise needed for this uniquely challenging exercise pertaining to all state Medicaid programs and the Medicare program over an 11 year span for 44 different national drug codes and related J-codes for claims submitted by tens of thousands of providers for millions of patients.

In this case, Dr. Duggan did not use a traditional random sample, but selected a method uniquely suited to the task at hand. The selected method is reliable because his exceptionally large samples (5.6 million claims, about two-thirds of the entire universe of claims) were paired with a painstaking analysis of all of the data during which he identified both similarities and differences between the populations. Crucially, where Dr. Duggan found differences in the data or in the underlying facts, he either declined to extrapolate or extrapolated only after making suitable adjustments to scale the extrapolation down (and never up). This is the common practice in applied microeconomic research. And, every last cent of Dr. Duggan's damages calculations is backed by reliable, verifiable claims data.

The basis for Abbott's motion *in limine* is fundamentally flawed because its critique is mired in the standards applicable to traditional random samples similar to those used to analyze fraud by a single entity. Abbott's failure to appreciate the differences between traditional random samples and Dr. Duggan's method results from its retention of experts who have no pertinent expertise regarding the econometric method employed by Dr. Duggan. Although there are parallels between Dr. Duggan's method and traditional random samples (and they use similar

terminology), they are not one and the same. Abbott's blind reliance on the standards of traditional random samples is flawed.

In addition, the specific underpinnings for Abbott's motion *in limine* are wrong. Dr. Duggan calculated damages with accurate data, his samples were sufficiently representative, and his support for extrapolating damages was strong. And, because it clipped the wings of its own experts by prohibiting them from performing any competing calculations or statistical analysis whatsoever, Abbott has failed to demonstrate that Dr. Duggan's method was not reliable. Abbott relies upon an economist to whom it denied access to the data, and whose primary opinion was that Dr. Duggan should have articulated more support for his approach to demonstrate its reasonableness, and a CPA who, despite having all relevant claims data and being paid $1.5 million to replicate the work of Dr. Duggan, did not quantify a single shortcoming in Dr. Duggan's work per the direction of Abbott counsel. Even were the testimony of Abbott's experts admissible, the most their inchoate analysis can support is the existence of differing opinions between experts to be resolved by a jury.

FACTS

Dr. Duggan calculated a fair, reasonable and conservative estimate of the difference between 1) what the government reimbursed for certain Abbott drugs provided to Medicare and Medicaid patients, and 2) what the government would have reimbursed had the prices reported been reflective of the actual prices at which Abbott transacted business.[1] His analysis involved five key steps:

[1] Dr. Duggan's work is generally described in the following documents: Duggan Expert Report ("Duggan Expert Rep.")(Abbott Ex. DT); Duggan Supplemental Report ("Duggan Suppl. Rep.")(Abbott Ex. DV); Duggan Rebuttal Report ("Duggan Rebutt. Rep.")(Abbott Ex. DW); July 23, 2009, Declaration of Mark Duggan, Henderson Common Ex. ("HC Ex.") 41 and September 21, 2009, Declaration of Mark Duggan, Ph.D., Henderson Reply Ex. ("HR Ex.") 90, and in the five days of deposition testimony, excerpts of which are attached hereto.

a. **Abbott Transactions:** Performing an analysis of the actual selling prices of Abbott's drugs by examining over $4.25 billion in sales, focusing on sales to the pharmacy class of trade which paid on average about 20 percent more than the overall average price, and then increasing that by another 25 percent to generate exceedingly forgiving alternate prices that were approximately 40 percent higher than the overall average price at which Abbott was selling its drugs;

b. **Claims Data:** Assembling a vast library of data from various sources which in combination offered a high degree of reliable claims data covering all of the Medicare claims and almost every quarter of every state's Medicaid program for each of the subject drugs;

c. **Medicare and Medicaid Reimbursement**: Gaining an understanding of the manner in which Medicaid and Medicare reimbursed for drugs accomplished, in part, by engaging an experienced consultant (Myers and Stauffer) to assemble summaries of each states' Medicaid program and re-create every available array used by Medicare carriers to set reimbursement for J-codes;

d. **Individual Re-Adjudication of over Five Million Claims**: Individually re-adjudicating over 5.6 million claims representing approximately two-thirds of all pertinent Medicare and Medicaid payments to calculate the reimbursement which would have been paid using non-inflated AWPs; and

e. **Extrapolating**: Using the experience and knowledge gained by individually re-adjudicating over 5.6 million claims, combined with painstaking comparisons of the populations, as the basis for performing thousands of individual calculations to generate separate estimates for each of the 44 quarters at issue for each of the 44 NDCs and J-codes.

1. Dr. Duggan Performed Each of the Five Steps in a Detailed and Reliable Fashion. . . .

a. Abbott's Transaction Prices

The starting point for Dr. Duggan's damage calculation was Abbott's actual transaction prices. He conservatively used the average indirect price paid by retail pharmacies as they paid 20 percent higher prices on average, leading to higher "alternative prices" and, therefore, lower damages. His calculations also left out prompt pay discounts and miscellaneous earned rebates, both appreciable concessions to Abbott of approximately 6 to 8 percent. In addition, Dr. Duggan

bumped up the average calculated prices by 25 percent.[2] Duggan Expert Rep., pp. 11-24 and HC Ex. 41, Attachment A.

b. The Government Assembled Claims Data and Information About Reimbursement Methodologies used by Medicaid and Medicare

Dr. Duggan used multiple, often overlapping, sources of state claims data and Medicare data which equipped him with one or more sources of claims data for every state, NDC and quarter for which he calculated damages, all of which are substantiated and reliable. A detailed discussion of the Medicaid data utilized by Dr. Duggan is set forth in the United States Common Memorandum of Law in Support of Cross-motions for Partial Summary Judgment, Dkt. Nos. 6317/314, at pp. 15-17. *See also* Duggan Expert Rep., pp. 24-29 and HC Ex. 41, ¶¶ 12-24. A brief description follows.

(1) Medicaid Data

For the state Medicaid analysis, Dr. Duggan used claims data from all 50 states. Some data was produced by approximately 30 states in connection with this litigation ("state-produced" data), and the remainder was collected by CMS from the states in the ordinary course of operating the Medicaid program. The CMS data includes the *claims-level* State Medicaid Research Files (SMRF), known most recently as the Medicaid Analytic Extract (MAX), and the aggregate State Drug Utilization Data (SDUD).

[2] This 25 percent increment was quite meaningful as it often resulted in Dr. Duggan's recalculated AWP being almost 20 percent higher than the 95th percentile price paid by Abbott's pharmacy customers (who were already paying higher prices than most of Abbott's other customers) and none of the prices included the additional prompt pay discounts and miscellaneous earned rebates. For example, the average indirect price paid by the pharmacy class of trade in the first quarter of 1995 for vancomycin, 00074-6533-01, was $6.692 and the extra 25 percent meant that Dr. Duggan's damage calculation would have been based upon a price of $8.365. In that same quarter, the 95th percentile price was $7.02.

(2) Medicare Data

Dr. Duggan used the complete Medicare Durable Medical Equipment (DME) claims data and Medicare Carrier claims data.[3] He also used the internal documentation, or arrays, of the Medicare carriers used to identify the median to be used as the allowed amounts.

(3) Medicare and Medicaid Reimbursement Methodologies

The United States retained an experienced consulting expert, Myers and Stauffer, to provide support to Dr. Duggan. At Dr. Duggan's direction, Myers and Stauffer compiled information as to each state's reimbursement methodology throughout the time period at issue. HC Ex. 24. Myers and Stauffer also organized and assembled numerous arrays used by 25 different Medicare DME and regular Medicare Part-B carriers to identify median prices. These arrays were used by the carriers to set the allowed amount on over 3.6 million individual claims. Myers and Stauffer re-created each of these arrays in spreadsheet form so that the impact of Abbott's mega-spreads on the resulting median could be computed and then used to assess the impact of Abbott's prices on the applicable J-code reimbursement.

c. Re-Adjudication of Over Five Million Individual Claims

The core of Dr. Duggan's work was to re-process the claims (and arrays) using the alternative Abbott prices, and then calculate the difference (*i.e.*, damages) between those results and what was actually paid. Duggan Expert Rep., pp. 30-126 and Tables 13A to 26B, and HC Ex. 41, ¶¶ 25-55.

(1) Medicaid

For Medicaid, Dr. Duggan calculated damages by individually re-adjudicating 2.0 million claims under the applicable state reimbursement algorithm using the state-produced claims data. These claims and damages formed the basis of Dr. Duggan's Medicaid sample.

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[3] This is claims level data and Abbott is wrong to call this aggregate data. Abbott Motion *in Limine*, p. 11.

(2) Medicare

For Medicare, Dr. Duggan calculated damages by individually re-adjudicating 3.6 million Medicare claims using the new allowed amounts generated by the use of the arrays with non-inflated Abbott prices. These claims and damages formed the basis of Dr. Duggan's Medicare sample. In performing the Medicare analysis, Dr. Duggan had the arrays that applied to 93,000 DME claims representing 90 percent of the claims paid and 3.59 million regular Part B claims representing over 76 percent of damages for these carriers with arrays. Only Abbott's prices were replaced in the arrays. Thus, any changes to the medians were solely the result of Abbott's inflated prices.

d. Extrapolation Calculations

Dr. Duggan examined *all of the data* (state-produced, SMRF/MAX, SDUD and Medicare) and performed numerous analyses to substantiate that the claims in his 5.6 million claims sample populations were a reliable basis for extrapolations. Dr. Duggan also scrupulously noted differences in the populations and either declined to extrapolate or extrapolated only after making suitable adjustments to scale the extrapolation down (and never up). *See, e.g.*, Duggan Expert Rep., pp. 24-29 and 77-126, Duggan Rebutt. Rep., p. 11, and HC Ex. 41, ¶¶ 56-108.

Dr. Duggan's first step for estimating the additional damages caused to the United States from claims which he analyzed, but did not individually re-process, was to analyze the damage calculations resulting from the individual re-adjudication of the 2.0 million Medicaid and 3.6 million Medicare claims.

(1) The Fraud Ratio

A key component of Dr. Duggan's extrapolation was the calculation of the ratio of damages to the total actually paid by the state Medicaid programs and the Medicare program (the "fraud ratio," called DIFF-FRAC in his reports). Duggan Expert Rep., pp. 78-81.

I. Results of the Medicaid Damages Calculations

When calculating the fraud ratio for the Medicaid programs, Dr. Duggan divided the damages figure by the total paid *(including the dispensing fee).* Dr. Duggan calculated 11,117 fraud ratios (one for each of the State-NDC-Quarter combinations for which he had state-produced data) and the average across states yielded 1,775 NDC-quarter fraud ratios used in the inter-state extrapolation. As a point of reference for comparison, the overall fraud ratio on the 2.0 million Medicaid claims was approximately 76 percent. Duggan Suppl. Rep., Table 25.

ii. Results of Medicare Damage Calculations

For Medicare, Dr. Duggan separately calculated a fraud ratio for each carrier, J-code and quarter. Duggan Expert Rep., pp. 81-123. The resulting fraud ratios demonstrated that the Medicare program's use of arrays to select median prices significantly attenuated the impact of Abbott's inflated prices. For the DME carriers, Dr. Duggan only calculated damages for one J-code, J-3370 (vancomycin) with an overall fraud ratio of approximately 47 percent of the total paid. Duggan Expert Rep., p. 93. For the regular Medicare Part-B carriers with matching array information, Dr. Duggan calculated damages on five J-codes – the four largest plus vancomycin – with an overall fraud ratio of approximately 23 percent. HC Ex. 41, ¶ 101. Due to the use of the median prices, both of these fraud ratios are appreciably lower than the comparable 76 percent ratio found on the NDC-specific Medicaid claims.

e. **Four Types of Extrapolation**

(1) Intra-state Medicaid Extrapolation

Dr. Duggan performed limited intra-state extrapolations for eight of the 10 states where the state-produced claims data did not cover substantially all of the eleven years at issue. HC Ex. 41, ¶¶ 77-82; Duggan Expert Rep., pp. 30-76 and Table 25. To do this, Dr. Duggan used the SMRF/MAX and SDUD data to calculate damages in those time periods. The nature of the intra-state extrapolations to calculate the remainder of the damages for these states is spelled out in Dr. Duggan's report in a separate, detailed sub-section for each state. *Id.* Dr. Duggan's

explanation of the process for Florida (*id*. at 37-44) provides an especially detailed discussion, including his comprehensive comparison of the Florida-produced data with the Florida SMRF/MAX and SDUD data, his decision to use SDUD data, and his resulting adjustments such as purposely choosing not to extrapolate to some time periods thereby lowering damages (*id.* at 37-38). He also describes how for each quarter for which he uses SDUD data, he reduces the fraud ratio applied to the computation based on a separate analysis of the applicable spread on the Abbott products. Thus, if the Abbott spread was smaller in earlier quarters, he lowers his extrapolation by a commensurate amount. In contrast, if the spread was larger in earlier years, he makes no upward adjustment. *Id.* at 42-45.

In total, for 86.8 percent of the 2 million claims for the 10 core states, Dr. Duggan used state-produced data. Dr. Duggan used SMRF/MAX/MSIS claims-level data for 8.7 percent, and aggregate SDUD data for an additional 4.5 percent of the claims. Duggan Rebutt. Rep., p. 10. In addition to all of the foregoing analysis, Dr. Duggan also double-checked his extrapolations through various means, including applying his replication method to periods for which he actually had claims level data, and comparing the test extrapolation figure to his actual calculation for that time period. Duggan Rebutt. Rep., pp. 11-12.

(2) **Inter-state Medicaid Extrapolation**

After individually re-processing 2 million claims, Dr. Duggan determined if he could perform an accurate, reliable estimate through extrapolation of the damages caused by Abbott's inflated AWPs in states where he had not individually re-adjudicated each of the claims. Again, Dr. Duggan performed numerous analyses to substantiate that the claims in his sample population were a reliable basis for extrapolations. His methodology is described in detail in his expert report. Duggan Expert Rep., pp. 77-81.

In sum, Dr. Duggan's special precautions to substantiate that the populations were similar included numerous factors. He was already familiar with: 1) Abbott's $4.5 billion in sales, 2) the

Medicaid reimbursement methodologies, 3) the state-produced data for the 10 core states and 20 others, 4) the SMRF/MAX and SDUD data for all 50 states, 5) the published AWPs, and 6) the impact of Abbott's inflated prices on two-thirds of Medicaid expenditures by individually re-processing 2 million claims. He additionally noted: 1) all of the states reimburse for the same Abbott Complaint drugs, 2) all of the states are subject to the same federal regulations, 3) all of the states use published prices when adjudicating claims, 4) all of the states in the two groups have a "lower of" methodology, 5) the stability of the fraud ratio across the 10 states despite their different adjudication methodologies, 6) the relative prevalence of the use of AWP, WAC, DP, U&C was similar, including that the vast majority of states used AWPs, 7) the fraction of states in the two groups that use the WAC is similar, and 8) the reimbursement scaling factors for the prices are on average similar between the two groups. Dr. Duggan calculated the average paid-per-claim in the 10 states as compared to the 38 states and saw that the 38 states paid even more for the drugs than the 10 states for the majority of the NDCs (24 of 44). Dr. Duggan performed an analysis of the 10 core states to compare the fraction of claims with damages and the fraud ratio, and concluded it was generally quite similar, whether the state used AWP, WAC, or DP. Based on the forgoing, Dr. Duggan concluded that an extrapolation of damages was reliable and within the standards of his profession, and applied the fraud ratios found in the 2.0 million claims to extrapolate damages separately for each NDC-QTR. Duggan Expert Rep., pp. 77-81; Duggan Rebutt. Rep., pp. 4-8, 12-14 ; HC Ex. 41, ¶¶ 56-76, 83-90.

The "extrapolation damages" were directly based on the SMRF/MAX and SDUD data, all of which Dr. Duggan carefully reviewed and compared for completeness and quality.[4] In general,

[4] Dr. Duggan reviewed the data in this step using the same approach he had used for the intra-state calculations. Thus, he reviewed each claim to confirm its reliability, excluding for example all claims that showed a paid amount of zero or which had a strictly positive third party payment amount. Duggan Expert Rep., p.77.

Dr. Duggan used the SMRF/MAX data when it was available and used the SDUD data when it was not. Duggan Expert Rep., p.77 and Tables 12A, 12B, 12C, 26A, 26B, 27A and 27B.

(3) **Intra-Carrier Extrapolation**

Dr. Duggan performed limited intra-carrier extrapolations for carriers where the arrays could be matched to only part of the time period in the same detailed and methodical manner as his intra-state Medicaid analysis. Dr. Duggan engaged in considerable analysis to substantiate the extrapolations, including confirming that the average amounts paid per J-code were comparable and that Abbott's AWPs were being used as the allowed amounts with similar frequency.[5] Where he found differences, he adjusted his calculations accordingly, often deciding that an extrapolation was not justified, or had to be adjusted downward. Duggan Expert Rep., pp. 95-126; Duggan Rebutt. Rep., pp. 14-18 and 12-14; HC Ex. 41, ¶¶ 91-108.

With respect to every Part B carrier, Dr. Duggan judiciously chose to not perform an intra-carrier extrapolation for at least a portion of the claims, typically because Abbott's AWPs were not being used as the allowed amounts with similar frequency. For example, even though there was evidence that Abbott's AWPs were being used, Dr. Duggan did not extrapolate at all for $1.7 million in claims paid by Connecticut General from the first quarter of 1991 to the first quarter of 1995, or for $.7 million in claims paid by Florida Blue Shield the first quarter of 1991 to the fourth quarter of 1992. Duggan Expert Rep., pp. 102, 122 n. 66 and Table 44.

Dr. Duggan performed this detailed analysis for each of the 21 Part B carriers for which he had matching arrays. The overall damage ratio calculated by Dr. Duggan for claims where he had the matching arrays was 28.5 percent. In contrast, as a result of his conservative

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[5] Dr. Duggan matched these prices to the actual published Red Book prices. *See, e.g.* Duggan Expert Rep., p. 93 (he uses "the price of the Abbott 74653401 product using data from the 1998 Red Book"); p. 85 (he notes that "[a]ll five of these prices are observed as medians in the arrays" which use Red Book prices). *See also* p. 8, 12, 88, 97, 100, 105, 116, 120. Abbott's claim of a subjective standard is baseless. Abbott Motion *in Limine*, p. 11.

adjustments, the damage ratio for the claims within these 21 carriers for which there were no matching arrays was forty percent lower, just 17.2 percent. Duggan Rebutt. Rep., p. 16.

(4) **Inter-Carrier Medicare Extrapolation**

The next step in Dr. Duggan's analysis was to estimate the damages caused by Abbott's inflated prices in the Part B carrier claims which could not be matched to arrays. As before, Dr. Duggan examined the Medicare data which revealed that the amount paid per claim for each J-code, the pattern of spending over time, and the proportion of claims accounted for by each of the five J-codes was similar among all carriers (with matching arrays or not). He considered and accounted for the frequency with which each of the two groups used Abbott AWP to set the allowed amount. Significantly, Dr. Duggan identified 1.3 million individual claims where the allowed amount was based on Abbott's AWP. These analyses were performed separately by J-code, carrier and array. Dr. Duggan also had ascertained that all carriers were hired by CMS to perform the same job, received the same instructions, and used Red Book AWPs. While utilizing the many arrays that matched with his 3.6 million individually re-adjudicated claims, he saw that one of Abbott's products was included in almost every array. HC Ex. 41, ¶¶ 92-94. Again, Dr. Duggan judiciously chose to perform no extrapolation of any damages for any claims from 1991 or 1992. Duggan Expert Rep., Table 44.

Ultimately, as a result of Dr. Duggan's adjustments, the percentage of damages in the extrapolation is just 16.7 percent of the total amount spent by these carriers, almost 30 percent lower than the corresponding ratio of 22.9 percent for the carriers with the matching arrays. Duggan Rebutt. Rep., pp. 17-18; Duggan Expert Rep., pp. 123 and 125. In addition, these percentages do not include any damages for 6 of the 11 J-codes excluded from consideration, accounting for approximately 11.3 percent of Medicare spending for the remaining carriers. *Id.* at 126.

DISCUSSION

Abbott does not challenge Dr. Duggan's qualifications or the relevancy of his testimony. Abbott does challenge the reliability of Dr. Duggan's testimony. Abbott's claims of do-nothing analysis and no-data damages are baseless. Abbott's attacks on Dr. Duggan can be used on cross-examination, but do not support exclusion of his testimony.

APPLICABLE LAW REGARDING EXPERT TESTIMONY

In determining the admissibility of expert testimony, the trial court must determine whether the expert is qualified and whether the expert's testimony is sufficiently reliable and "relevant to the task at hand." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993) "The proponent need not prove to the judge that the testimony is correct, but she must prove by a preponderance of the evidence that the testimony is reliable." *Id.* at 130 (quoting *Moore v. Ashland Chem., Inc.*, 151 F.3d 269, 276 (5th Cir. 1998)). The critical inquiry is whether the expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999); *Crowe v. Marchland*, 506 F.3d 13, 17 (1st Cir. 2007).

Although the district court's gate-keeping function is essential, "the [c]ourt must, however, keep in mind the Supreme Court's admonition that, '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.'" *In re Neurontin*, 612 F. Supp. 2d 116, 131 (D. Mass. 2009) citing *Daubert*, 509 U.S. at 596). Moreover, "[a]n economist's failure to consider certain data is not fatal to the admissibility if the expert sufficiently explains her choice of data for her analysis." *In re Pharmaceutical Industry AWP Litigation*, 491 F. Supp. 2d 20, 86 (D. Mass. 2007). In this case, Dr. Duggan's analysis displays the intellectual rigor of economists outside of the courtroom. Any flaws in Dr. Duggan's analysis alleged by Abbott go "to the weight, not the admissibility of the testimony." *Id.*

THE MEASURE OF AND BURDEN OF PROOF FOR FALSE CLAIMS ACT DAMAGES

The United States has asserted two alternate damage theories in this case. The first seeks 100 percent of the money paid to the customers of Abbott (approximately $343 million less total Medicaid state shares of approximately $66 million).[6] The second seeks the difference between what was actually paid because of Abbott's mega-spreads and what would have been paid had Abbott reported prices rooted in reality (approximately $107 million). Abbott's motion is solely directed at the second, more conservative theory.

a. Applicable Law Regarding FCA Damages

The United States may measure its damages by the amount that it paid out by reason of the false statements over and above what it would have paid if the claims had been truthful. *United States ex rel. Marcus v. Hess*, 317 U.S. 537 (1943); *United States v. Woodbury*, 359 F.2d 370, 379 (9th Cir. 1966); *United States v. Ekelman & Assocs*., 532 F.2d 545, 550 (6th Cir.1976); *United States v. Killough*, 848 F.2d 1523, 1532 (11th Cir. 1988).

While the government must prove damages beyond "speculation and guesswork," it need not do so to a mathematical precision. *Bigelow v. RKO Radio Pictures*, 327 U.S. 251, 263-264 (1946); *United States v. Killough*, 848 F.2d 1523, 1531 (11th Cir. 1988). In cases where a defendant's bad acts have made calculation of damages difficult, as Abbott's conduct has done in this case, the law eases the standards for damage measurement. *Story Parchment Co. v. Paterson Parchment Paper Co.*, 282 U.S. 555, 563 (1931).

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[6] The FCA attaches liability to the claim for payment. Once the claims were submitted to the government based on false pretenses, Abbott's customers had no right to receive payments for those services. *United States ex rel. Anti-Discrimination Center of Metro New York v. Westchester County*, 2009 WL 1108517 (S.D.N.Y. April 24, 2009); *U.S. v. Mackby*, 338 F.3d 1013 (9th Cir. 2003). No offset to the defendant is required. Congress specifically rejected a "no harm, no foul" argument: "such claim[ ] may be false even though the services are provided as claimed if, for example, the claimant is ineligible to participate in the program...." S. Rep. No. 99-345, at 9, reprinted in 1986 U.S.C.C.A.N. 5266, 5275. This approach is directly supported by the deterrent nature of the FCA. Courts are accordingly guided by the principle that the United States' damages should be liberally measured to effectuate the remedial purposes of the Act.

b. Extrapolation in Calculating Damages

The United States performed a detailed review of a sizeable portion of the claims, then extrapolated to a subset of the other claims after confirming that the populations were comparable. This is an acceptable method. *United States ex rel. Loughren v. Unumprovident Corp*., 604 F. Supp. 2d 259, 261 (D. Mass 2009). *See* U.S. Common Reply Memorandum, Dkt. 6519, pp. 18-20. Also, the failure to include all possible factors in a reasonable estimation of damages is not fatal. *United States ex rel. Tyson v. Amerigroup Illinois, Inc.*, 488 F. Supp. 2d 719, 732 (N.D. Ill. 2007).

The cases cited by Abbott are distinguishable from the facts here. In *United States ex rel. Whipple v. Rockwell Space Operations Co.*, 2002 WL 864246, at 12* (S.D. Tex. Apr. 3, 2002), the court rejected an extrapolation from a lay person and in *United States v. Skoknek*, 933 F. Supp. 1108, 1115-18 (D. Mass. 1996) no expert performed the statistical extrapolation – the investigative unit attempted the calculations.

While Abbott cites *U.S. ex rel. Loughren v. UnumProvident*, 604 F. Supp. 2d 259 (D. Mass. 2009), that decision expressly concluded that "extrapolation is a reasonable method for determining the number of false claims so long as the statistical methodology is appropriate." 604 F. Supp. 2d at 261. This Court rejected the expert's statistical sampling methods only after finding that the expert's methods lacked peer-review and that an authoritative text cited by the expert did not once actually mention his method of "cohort sampling." *Id.* at 266. Also, in that case, the opposing expert convincingly demonstrated the unreliability of the method by actually performing unequivocal, competing calculations.

Abbott cites *Albert v. Warner Lambert Co.*, 604 F. Supp. 2d 101 (D. Mass. 2002) as a case where a court refused to allow the jury to hear expert damages calculation. In *Albert*, the court states that "the fatal flaw in the survey . . . is the size of the sample on which the results are based." *Id.* at 106. The sample in Albert was twenty Medicare-eligible nursing homes in two

states used as the basis for the nationwide universe of nursing facilities without providing any justification for doing so. *Id.* at 106, n.7. In *Allgood v. General Motors Corp.*, 2006 WL 2669337 (S.D. Ind. Sept. 18, 2006), the court excluded expert testimony regarding PCB contamination because the expert could not provide a scientific explanation for choosing the samples that he did. *Id.* at *11. In *Collyer Insulated Wire Co.*, 94 F.Supp. 493 (D.R.I. 1950), the district court refused to allow government witnesses to testify as to damages because the testimony amounted to "hardly more than speculations and guesses." *Id.* at 499. These rulings cannot be compared to the case at hand. Dr. Duggan is a Harvard-trained economist who used methodologies accepted in his field and his findings are not the result of "speculations" or "guesses." Moreover, he used a more than adequate sample size and he thoroughly described the basis for his sampling choices.

c. Non-Random Samples are Routinely Used in Litigation

Abbott suggests that the *Reference Manual on Scientific Evidence*, pages 90-100, mandates the use of random samples in all instances. Abbott Motion *In Limine* at 16. That is incorrect. Abbott does not point the Court to page 244 of the manual which notes that non-probability samples are often used and found to be reliable, especially in some types of litigation (Lanham Act cases), and that confidence intervals are not used. Even one of Abbott's experts concedes that samples need not be random. Hughes Deposition Transcript Excerpts attached as Exhibit 1 ("Hughes Dep., Ex. 1") at 401:2-402:13. The *Reference Manual* does caution that the expert should be prepared to justify the method used to select the sample and that special precautions are required to reduce the likelihood of biased samples. The massive samples relied upon by Dr. Duggan in combination with detailed analysis of all data satisfies this caveat. And, of course, the *Reference Manual* is remarking upon the typical sample of a few dozen or few hundred units, not the 5.6 million claims used by Dr. Duggan. Dr. Duggan's methodology is vastly superior to even the non-probability samples cited approvingly in the *Reference Manual*.

DR. DUGGAN IS QUALIFIED TO TESTIFY, AND HIS TESTIMONY IS RELEVANT AND RELIABLE

a. Dr. Duggan is Qualified to Testify and His Testimony Is Relevant

The witness must be qualified by "knowledge, skill, experience, training or education." Fed. R. Evid. 702. Dr. Duggan's superior qualifications in the field of economics are without dispute. He is currently the Senior Economist for Health Care on President Obama's Council of Economic Advisors. His research has been published in some of the nation's top economics journals. Duggan Curriculum Vitae ("CV"), pp. 1-3 attached hereto as Exhibit 2 (originally marked as Abbott Ex. 1094 at the deposition of Dr. Duggan). Dr. Duggan received his Ph.D. in Economics from Harvard University and went on to teach economics at the University of Chicago and MIT before becoming a Professor of Economics at the University of Maryland. Duggan CV, p. 1.

Dr. Duggan is very experienced at performing studies on government programs like Medicaid and Medicare. Duggan Expert Rep., pp. 5-6. Dr. Duggan has applied advanced quantitative methodologies to analyze large-scale data sets and investigate questions in micro-economics of interest to academics and policymakers. *Id.* at 6. For expert testimony to be relevant, it must "assist the trier of fact to understand the evidence or to determine a fact in issue." *In re Scrap Metal Antitrust Litigation*, 527 F.3d 517, 528 (6th Cir. 2007) (citing Fed. R. Evid. 702); *accord Ruiz-Troche v. Pepsi Cola*, 161 F.3d 77, 81 (1st Cir. 1998). Dr. Duggan's opinion would assist the trier of fact in determining liability and assessing damages.

b. Dr. Duggan's Testimony is Reliable

Dr. Duggan extrapolated his results (from extremely large samples) only after substantiating that the populations were comparable using methods that are consistent with those used by economists in academic research. Dr. Duggan's approach for calculating damages in this

case is the same approach that he takes with his work outside the litigation context. Dr. Duggan testified:

> I think the analysis that I undertake here is very similar to the analysis that I've undertaken in a large share of my empirical work which is to get at the causal effect of one or more things on an outcome variable of interest. And so I believe that my prior research is very relevant for this analysis.

Duggan Deposition Transcript Excerpts attached as Exhibit 3 ("Duggan Dep., Ex. 3") at 48:1-7. In several peer-reviewed studies, Dr. Duggan has analyzed the effect of a specific factor or set of factors on federal spending while holding other factors constant. Duggan Dep., Ex. 3. at 214:16-21.

Abbott's claim that it could not locate support in the literature for the methodology utilized by Dr. Duggan is puzzling given that such literature was specifically cited in Dr. Duggan's reports. For example, Dr. Duggan cited Gruber and Rodriguez in their 2007 *Journal of Health Economics* study which used data for a sample of just one percent of all physicians, with the physicians' characteristics differing substantially from the average physician in the United States. Duggan Rebutt. Rep., p. 17. Dr. Duggan also cited a study by Bruce Meyer that was published in *Econometrica* in 1990 which utilized administrative unemployment insurance data for twelve states to estimate the effect of the unemployment insurance program on trends in the national labor market (*id.* at p. 13) and research by Adams, Gruber, and Newhouse published in the *Journal of Human Resources* in 1997, which examined the effect of physician fee changes in Tennessee while using Georgia as a control to shed light on the effect of Medicaid physician reimbursement on the treatment of Medicaid recipients. (*Id.*)

ABBOTT'S SPECIFIC ARGUMENTS ARE UNPERSUASIVE

Dr. Duggan's methodology, using 2.0 million Medicaid claims and 3.6 million Medicare claims together with painstaking analysis of the populations and surrounding facts and a judicious approach to extrapolation, is reliable and helpful to the Court and the jury. Abbott's

criticisms are based on false assumptions, studies with comparatively tiny sample sizes, and are unsupported by an actual showing of unreliability.

Abbott claims in various ways that Dr. Duggan ignored relevant variables. This is misleading. In fact, Dr. Duggan's reports and testimony establish that he considered, but rejected as immaterial, the variables cited by Abbott. For example, Abbott claims that Dr. Duggan ignored testimony regarding Medicaid dispensing fees. There are reasons why this issue is legally irrelevant. But, Dr. Duggan testified that, when estimating the causal effect of one variable on another variable, it is common practice in applied microeconomics to hold other factors constant and focus upon the direct rather than indirect effects. Dr. Duggan candidly acknowledged that some indirect factors could reduce damages, but countered that it was just as likely that other indirect factors could increase damages. Dr. Duggan also cautioned that some amount of unreliability can result from a researcher's untestable assumptions, and his subjective judgment about which factors to change. Dr. Duggan tested his analysis on the direct, testable factors while holding other factors constant as is commonly done in economic analyses. Duggan Rebutt. Rep., pp. 3-4. In short, Dr. Duggan considered, but rejected the variables identified by Abbott.

a. The Basis for Dr. Duggan's Sample is Well-Articulated and Economically Sound, and Abbott's Claims of Bias Should be Reserved for Cross-Examination

Dr. Duggan focused on 10 states and 25 carriers that accounted for a significant percentage of Medicaid and Medicare expenditures. This was a judgment he made as an economist with a sound basis in the data and related facts. Abbott complains that Dr. Duggan did not discuss how he chose the 10 states. That is incorrect. Dr. Duggan explained that he "focused attention on the largest states to obtain the maximum amount of precision," and that it was more important to the total value of damages "to be as accurate as possible for the state of Florida, with more than $16 million in Medicaid spending on Complaint products, than it is in

the state of Vermont, which spent less than $51 thousand on these same products." Duggan Rebutt. Rep., p. 14. Dr. Duggan further testified on this issue:

> ... I wasn't opposed to having data for other states, but I felt for the purposes of my analysis it would be—just sort of diminishing returns sense. It would be most important to start with the places that account for the largest amount of Medicaid spending.

Duggan Deposition Transcript Excerpts attached as Exhibit 4 ("Duggan Dep., Ex. 4") at 243:16-21; *see also, id.* at 250:10-251:1, Duggan Deposition Transcript Excerpts attached as Exhibit 5 ("Duggan Dep., Ex. 5") at 535:3-9. Abbott's suggestion that Dr. Duggan purposely declined to include Texas as part of the 10 core states in order to bias the sample has no evidentiary basis. Nor has Abbott shown how the modest Texas utilization of $2 million and damages of $.9 million would have materially impacted the overall analysis given that the Texas utilization would have accounted for only 2 percent of the $90 million in expenditures of the 10 states.

Dr. Duggan determined that the data he chose to rely upon was more than adequate for calculating a reasonable estimate of damages. He testified: "[I]t is rarely true—I'm not sure it has ever been true—that a study has perfect data." Duggan Dep., Ex. 4 at 247:1-3. Dr. Duggan used "the necessary amount of data acquisition to arrive at an accurate, though conservative, finding." *Id.* at 245:15-17. He specifically evaluated the similarities and differences between the populations and made appropriate adjustments, often declining to extrapolate damages. For every cent of damages, Dr. Duggan used reliable, verified data.

Abbott criticizes Dr. Duggan for doing nothing to ensure that the 10 states were representative of the 38. Abbott Motion *in Limine*, pp. 2, 7. This is false. Dr. Duggan took special precautions of using samples of unprecedented size, while also performing extensive analysis of the data-sets and surrounding factual circumstances to further validate his approach. *See supra*, pp. 8-9. In sum, Dr. Duggan confirmed the similarity of the populations by an analysis of the surrounding facts (*i.e.*, the similarity of the state methodologies, reliance on

published prices, *etc.*) and by an analysis of the data (*i.e.*, an analysis of the amounts paid per NDC within the 10 states and as between the 10 states and the 38 states). Dr. Duggan's methodology should not be evaluated on the basis of routine random samples used to assess overpayments (or fraud) for a single provider and is not obligated to utilize CMS protocols created for those inapposite situations, as suggested by Abbott. Abbott's wide-reaching fraud is a different creature that required a different method. Abbott has likewise failed to identify any objective basis obligating Dr. Duggan to carry out additional analysis and has failed to show that doing so would have changed the result.

b. Abbott's Examples are Unquantified, One-sided, and Cherry Picked

Abbott asks this Court to exclude testimony of Dr. Duggan based upon its own cherry-picked, isolated and biased examples. Abbott's observations are incorrect. While Abbott is free to try to use these examples on cross-examination of Dr. Duggan, they certainly do not form a basis to exclude his testimony. None of Abbott's examples effectively undermine Dr. Duggan because they disregard the remainder of the population and include no quantification of any actual impact.[7]

1. Dr. Duggan Did Consider the Differences Between States' Varying Approaches to Ingredient Costs

As one example, Abbott uses the reimbursement of vancomycin in Maryland to argue that Dr. Duggan's extrapolation is not reliable. Abbott neither quantifies any alleged impact nor bases its example upon actual work performed by Dr. Duggan – in other words, this is a straw-man attack. Abbott contends that extrapolating damages to Maryland using a fraud ratio of 81 percent is inappropriate because doing so would result in damages of $7.80, and effectively allow

[7] By refusing to provide their experts with data and forbidding them from performing any calculations or extrapolations, Abbott has left the choice between Duggan's reasoned, supportable and conservative method versus the implausible notion that Abbott's grossly inflated prices did not cause any harm in the remaining 38 states.

for a net payment of just $1.84. However, by isolating Maryland, and taking all of the other states out of the equation, Abbott blinds itself to states where a fraud ratio of 81 percent results in damages being understated.[8] Dr. Duggan evaluated the appropriateness of an extrapolation to 38 states *in toto* and implemented his extrapolation in that fashion. Abbott's solo state examples warp Dr. Duggan's approach and fail to demonstrate that his approach is not accurate when implemented across the board. Also, total Maryland Medicaid expenditures at issue were a modest $1.8 million. Duggan Expert Rep., Table 27A. The combined expenditures of the other 37 states in the extrapolation exceed $45 million, over 24 times the Maryland total. *Id.*

The 2004 OIG Report cited by Abbott to support its claims regarding the variability of state payments is not persuasive. Abbott's Motion *in Limine*, p. 19. Most importantly, Dr. Duggan has performed a similar analysis specific to the drugs in this case and found little variability while the OIG report did not consider the drugs at issue in this case. The OIG report was also challenged by CMS as being inaccurate citing OIG's claim that reimbursement ranged from $51 to $1,295 on a pill with a federal upper limit of 34 cents per tablet. Abbott SJ Exhibit ER, p. 36.

Abbott's additional examples relating to other limits on ingredient costs or higher dispensing fees fare no better. The general, unquantified results of such isolated analyses would

[8] For example, many states would have reimbursed on the basis of Abbott's then-published AWP of $66.01 even though the average selling price for Abbott's vancomcyin in 1997Q1 was just $5.85 and the alternative AWP calculated by Dr. Duggan was $7.31. HC Ex. 41, Attachment A, p. 13. If such a state were comparable to Maryland and also used AWP minus 10 percent (such as Mississippi and Colorado) reimbursement would be $59.41 ($66.01 times 90 percent). In that case, Dr. Duggan's 81 percent fraud ratio would lead to damages of $48.12 and would effectively allow a net payment of $11.29. In contrast, the reimbursement based on an accurate AWP of $7.31 minus 10 percent would be $6.58. Thus, under Abbott's reasoning, Dr. Duggan's damages are understated in most states, but Abbott ignores that obvious corollary to its attack.

be unhelpful to this Court or a jury.[9] Abbott chose not to take the required next steps in any quantification – preferring more unhelpful mud-slinging just to see what might stick.

2. Dr. Duggan Did Consider the Differences between the Reimbursement Methodologies of the States Due to Varying Dispensing Fees

Abbott claims that Dr. Duggan ignored dispensing fees. According to Abbott, because the SMRF/MAX and SDUD data includes dispensing fees, Dr. Duggan's dollar-value difference includes not just drug payments, but also dispensing fees. Abbott is wrong again.

When Dr. Duggan calculated his fraud ratios, he specifically factored in the dispensing fees. An example is illustrative. Consider a claim actually paid on the basis of an ingredient cost of $10 plus a dispensing fee of $4 for a total of $14. If Dr. Duggan calculated an alternative ingredient cost of $2, the revised payment together with the dispensing fee would be $6, a drop of $8 from the original $14. In that situation, Dr. Duggan calculated the fraud ratio as $8 over $14 (57 percent), not $8 over $10 (80 percent). Thus, Dr. Duggan specifically dealt with this issue in a fair and reasonable fashion.

Abbott's unquantified argument that 15 of the 38 states developed enhanced dispensing fees for home infusion and compounded drugs is unpersuasive. Plus, Abbott identifies only four states (including Utah which did not implement an enhanced fee until 2001Q2) representing less than 10 percent of the expenditures of the 38 states. Abbott then notes that only two states among Dr. Duggan's core states (Michigan and Wisconsin) have enhanced dispensing fees, apparently to suggest that the proportion of enhanced dispensing fee states in the 10 states is different than in the 38 states. However, Abbott does not take into account that Dr. Duggan weighted each of the 10 states equally when he extrapolated. Duggan Expert Rep., p. 78. Thus,

[9] Also, the jury should not be deprived of Dr. Duggan's entire analysis when it might decide to just drop the damages associated with one or more of the 38 states to address Abbott's concerns. The baby need not be thrown out with the bath water.

the two states accounted for 20 percent of the impact (2 out of 10), more than double the impact of the four states identified by Abbott. Abbott's general, unsupported and unquantified claims regarding other states have little weight and should be disregarded. Dr. Duggan considered the reimbursement methodologies of the 50 states, performed data analysis to compare and contrast the states, and then exercised his professional judgment by concluding that the similarities outweighed the differences. Abbott's expert might disagree with the ultimate conclusion, but that is not the same as proving the unreliability of Dr. Duggan's method which Abbott has not done (an especially difficult task given Abbott's decision to not perform an competing calculations).

Although Abbott contends that a deeper analysis of dispensing fees is warranted, it does not address the additional factors introduced by such an inquiry. For example, in order to make an unrelated point, Abbott has noted that the drug Remicade, even with a modest spread of 25 percent or so, provides a margin of around $200. Young Rep., ¶ 65. What Abbott ignores is that its 25-cent, 700 percent spread teaspoon (10ml) of salt water (00074-4888-10) is not administered to a patient as a stand-alone treatment; it is used to reconstitute a freeze-dried product, such as Remicade into a liquid, and once reconstituted, it is administered to a patient with yet another bag of Abbott's 1600 percent spread salt water. *See, e.g.*, Dubberly Deposition Transcript Excerpts attached as Exhibit 6 ("Dubberly Dep., Ex. 6") at 103:21-104:14 (describing that Georgia Medicaid reimburses a "simple admixture of a medication with a diluent like sterile water, normal saline" under the normal methodology). Throughout this litigation, Abbott uniformly and vigorously fought discovery regarding any drugs except the 44-specific NDCs named in the United States' complaint. It cannot now seek to undermine the analysis of the

United States by claiming the relevance of every other drug administered together with any of the Abbott NDCs.[10] And without that information, Abbott's criticism is wholly speculative.

3. Dr. Duggan Did Consider the Differences between the Medicare Carriers' Use of Arrays

Notwithstanding the overwhelming evidence of its liability for false claims, Abbott asks this Court to disallow damages where arrays could not be retrieved from storage or otherwise located. However, there is substantial evidence, direct and circumstantial, to support Dr. Duggan's reliable method to evaluate the damages in connection with those claims.

The Medicare carriers (with and without arrays) all contracted with CMS to perform the same function of reimbursing for the same J-codes using median prices based upon the same price source (Red Book). For the arrays that were located, Dr. Duggan confirmed that one of Abbott's inflated prices was included in almost every array. In the data for the carriers for which arrays could not be located, Abbott's AWP was used as the allowed amount in 1.3 million claims. United States' Local Rule 56.1 Statement of Undisputed Material Facts Common to All Defendants, ¶¶ 158-159 and HC Ex.41 (Duggan Decl.), ¶¶ 92-94. Dr. Duggan also confirmed that the average amounts paid by all of the carriers was quite similar, and he studiously analyzed the relative prevalence of the use of Abbott's AWPs among the carriers over different time periods. Using the skills and tools of an economist, and as generally accepted in peer-reviewed publications, Dr. Duggan adjusted his calculations to account for differences and declined to extrapolate damages on numerous occasions. *See, supra*, p. 10.

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[10] The $200 Remicade spread, combined with the $10 spread on each bag of salt water or dextrose used to administer the Remicade (or any of the hundreds of other intravenous drugs), aptly demonstrates why it is the government – rather than a financially-motivated pharmaceutical manufacturer – that sets reimbursement. Another example is Abbott's setting the AWP on its generic vancomycin at five times the AWP of the brand name product, then asserting that the spread would save money by promoting the use of generics.

Abbott claims (again without quantification of any actual impact) that variability in the pricing arrays – a result of different-sized packages by different manufacturers being used in the arrays – undermines Dr. Duggan's analysis.[11] Abbott is wrong. While there was variability in arrays by particular carriers, Abbott did not show that variability in the Medicare claims that were matched to arrays would be any different than the variability in the Medicare claims that could not be matched to arrays. In fact, the opposite is true. Dr. Duggan specifically analyzed the data for the two groups and showed that there were only minor differences between the carriers, and for those minor differences, he made appropriate adjustments. More mud that doesn't stick.

4. No Market-Share Analysis is Necessary When Only Abbott Prices are Replaced in the Arrays

Abbott criticizes Dr. Duggan for not performing a market-share analysis. This was unnecessary. When Dr. Duggan re-created the carrier arrays used to identify the median if Abbott had not inflated its prices, only Abbott's prices were changed. Any change in the medians Dr. Duggan used to calculate damages were those solely caused by Abbott's conduct.

A market share analysis would only make sense if the arrays had been re-created with lower prices for all manufacturers. For example, on page 97 of Dr. Duggan's Expert Report, he demonstrates that when he recreated the array for the J7050 code (250ml Sodium Chloride solution) he only replaced the Abbott price, and the median modestly dropped from $10.69 to $9.11, a total of $1.58, even though Abbott's AWP was inflated by $10.48 ($11.61 minus $1.13). If the United States had also replaced the other prices in the array with accurate prices, the new median would have been comparable to Abbott's alternative AWP of $1.13 and the damages would then have been calculated based on the basis of a drop in the median of approximately $9.56 ($10.69 minus $1.13). If that approach were used, the damages would have been six times

[11] Abbott also claims that some carriers did not use AWP medians. Its citation for that proposition (Abbott SOF 149) says no such thing.

higher than calculated by Dr. Duggan ($9.56 versus $1.58), and a market analysis to apportion the damages among the three defendants jointly causing that 600 percent leap might have been a possible consideration. But where the damages caused by Abbott have been isolated at the modest amount of $1.58, it is appropriate for Abbott to be held responsible for all damages resulting from its conduct.

c. Abbott is Responsible for Causing Damages Whenever Inflated Prices Cause the Reimbursement to be Higher

Abbott ignores the states' universal use of a "lower of" methodology and claims that it is not liable if the payment for a drug was based on any price other than a published compendia price, or on a formula that did not exactly match the state's reimbursement methodology. Abbott's Motion *in Limine*, p. 5. The government thoroughly discredited this position in its summary judgment reply memorandum, Dkt. No. 6519, pp. 14-18. The evidence is overwhelming that by fraudulently inflating its prices, Abbott catapulted the Medicare and Medicaid reimbursement upward; the failure of the reimbursement to reach what otherwise would have been its apex because some states' countered Abbott's fraud through MACs does not break that initial causal link in the presence of a "lower of" algorithm. *See Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d 127, 147 (D. Mass. 2008) (explaining why providers' entry of inflated usual-and-customary charges did not insulate defendants from liability because of a state's lower of methodology). Thus, Dr. Duggan's approach to evaluating damages was fully warranted.

1. Abbott's Expert Has Prepared Charts Which Prove That Lower AWP's Would Cause Lower Reimbursement Regardless of the Presence of Alternative Prices

Abbott's CPA prepared charts to analyze the prices at which Abbott's products were reimbursed and included one in his expert report. Young Expert Rep. *(*Abbott Motion *in Limine,* Ex. D), ¶ 42 figure 4*; see* U.S. Summary Judgment Memorandum, Dkt. 6519, p. 17. The chart

was apparently designed to show the variability in the allowed reimbursement, but is of limited utility for that purpose.[12] What the chart does demonstrate is that the large majority of reimbursement was reliably driven upward annually every time Abbott caused a higher AWP to be published. In each year from the early 1990's through 2000, the most common reimbursement prices were pushed upward as can be seen by the close concentration of dots where they have coalesced into lines at the AWP-level, and, underneath the lines, can be seen a scattering of prices at different levels, due in all likelihood to reimbursement based upon U&Cs, and perhaps MACs.

An interesting phenomenon can be seen in these charts in the year 2001, after Abbott received a scathing letter from Congressman Stark and finally decided to report prices that were more modestly inflated. What is obvious is that when the lower AWP's were automatically used by the states, the reimbursements immediately came down in lockstep with the AWPs. Moreover, the relatively few reimbursements that were not clustered at the AWP-level were gone; after 2001, those paid amounts would have been higher than the new AWPs. The reimbursement was based upon the lower price as a result of the lower-of methodology, and any higher prices became irrelevant.[13] Dr. Duggan's damage analysis merely extends this reality back in time.

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[12] The scale of the charts is potentially misleading as to the numbers of claims because a common price might have multiple points stacked one on top of the other, and thereby still appear as a single point on the chart. There would be no way to easily distinguish a true single point from a stacked point.

[13] If Abbott had reported accurate prices to Red Book or First Databank, those prices would necessarily have been used by the Medicare and Medicaid programs, and the lower AWPs would have trumped any higher-alternative prices as a result of the application of the lower-of methodology. Abbott's desire to speculate about whether the federal government or the states would have changed the system to use the lower prices turns the issue on its head. Both were already using a system that would have used the lower prices and Abbott has introduced no evidence to suggest otherwise. None of this speculation should result in exclusion of testimony from the government's expert witness on damages.

d. Abbott's Experts Are Unreliable and Their Opinions Do Not Support the Relief Requested in this Motion

Abbott has attached copies of the reports prepared by its experts, but only cites to them in a footnote. Stephen Young is a CPA with a Bachelor's degree in accounting who agrees that his accounting expertise was not brought to bear on this case. Young Deposition Transcript Excerpts attached as Exhibit 7 ("Young Dep., Ex. 7") at 136:16-22, 137:16-138:11, 140:17-22 and 214:19 -215:7. Mr. Young reviewed the data, but only for the purpose of replicating Dr. Duggan's calculations. Based on what he did review he found only modest differences, all of which were either immaterial or corrected. Although he was paid $1.5 million, he did not perform any quantitative or statistical analysis of Dr. Duggan's work: "My opinions in this matter are not related to opining upon the statistical methodologies or basis [of Dr. Duggan's work]." Young Deposition Transcript Excerpts attached as Exhibit 8 ("Young Dep., Ex. 8") at 566:6-9. Indeed, he has no such expertise other than some undergraduate course-work in statistics and economics. *Id.* at 136:16-22, 137:16-11, 140:17-22, 214:19-215:7. The only expertise he brought to bear on the case was his view of the standard manner in which overpayments were calculated in the health care arena: "My opinions are based on what the standards are in the industry based on what I've seen for individuals to calculate to sustain a position that there's been overpayments." *Id.* at 566:10-17; 565:9-11 ("I do not believe that the opinions in my report are based on the statistical analysis that [Dr. Duggan] has performed"); *Id.* at 562:19-21 ("the standard that I am applying is what I have seen historically necessary to support an overpayment of a claim to a provider"); *Id.* at 563:17-19 ("my role was not to get into the statistics or lack thereof associated with his analysis"). Mr. Young's opinions do not in any way support the drastic relief requested by Abbott's motion.[14]

[14] Mr. Young's numerous mistakes and misrepresentations also undermine the weight of his testimony. In his report, he suggested that Dr. Duggan's calculations were to be doubted

The other expert upon which Abbott relies is James Hughes. Dr. Hughes has a Ph.D. in economics and is a Professor at a liberal arts college. He has never performed any analysis of SMRF/MAX data, has minimal experience with individual Medicaid or Medicare claims data or SDUD data, has never extrapolated damages in a Medicaid case, and has never calculated J-code damages. Hughes Deposition Transcript Excerpts attached as Exhibit 9 ("Hughes Dep., Ex. 9") at 129:19-130:16, 134:2-20 and 145:2-15. Abbott counsel chose to prevent all data used by Dr. Duggan from reaching Dr. Hughes and did not allow him to perform a quantitative analysis of the work performed by Dr. Duggan. Hughes Dep,. Ex. 1 at 616:12-13.

The primary thrust of Dr. Hughes' opinion was that Dr. Duggan should have more fully articulated the underlying basis for portions of his analysis to show it was reasonable. Other than reasonableness, Dr. Hughes could articulate no objective standard based upon economic principles or otherwise. *See e.g.*, Hughes Dep., Ex. 1, 345:1-9 ("When you're doing data analysis, you want your data to be as accurate as possible. That's the standard."); Hughes Dep., Ex. 9 at 250:11-17 ("what I have said several times now is that when one makes an assumption, the assumption needs to be reasonable"); *id.* at 256:14-21 ("he and I could kick that one around and I may well come to agree with him yeah, under the circumstances that's reasonable."). Dr. Hughes' opinion was based upon his suspicion that there were factors that would have lowered Dr. Duggan's damages calculations. Notably, he could think of no factors that might raise Dr. Duggan's damages. Hughes Dep., Ex. 1 at 422:15-423:16. At best, Dr. Hughes' opinions

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because he had discovered a difference in the damage calculations for Hawaii, but when confronted with his work papers agreed that the difference of nine dollars ($9.00) was immaterial. Young Dep., Ex. 8, pp. 303:4-314:10. He represented in his report that Dr. Duggan's prices were too low because some Abbott customers paid even higher prices, but his first two attempts at providing examples failed because he incorrectly calculated the purchase prices. His third attempt identified two customers who paid a few dollars more on small purchases. Young Dep., Ex. 7 at 179:7-195:3 and Young Dep., Ex. 8 at 405:15-422:9.

provide ammunition for Abbott to cross-examine Dr. Duggan at trial. No opinion offered by Dr. Hughes comes close to warranting exclusion of any or part of Dr. Duggan's opinions.[15]

Dr. Duggan, an expert on the methodology he applied, pointed to economic literature discussing this approach. Importantly, Abbott's two experts were not familiar with the econometric method used by Dr. Duggan and other economists. It is difficult, then, to fathom how they can critique this approach or its application in a way that is helpful to this Court or a jury.[16]

CONCLUSION

Abbott's motion *in limine* is rife with mud-slinging, but none of the mud sticks. Abbott's expert witnesses lobbed various, untested hypotheses about ways in which Dr. Duggan might have analyzed data differently. All of this makes Abbott that much more prepared for cross-examination at trial but none of its various and sundry arguments support the drastic relief requested – exclusion of some or all of Dr. Duggan's opinions.

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[15] For example, although Dr. Duggan repeatedly references and relies upon the Red Book as a resource for Abbott's AWPs cited in his report, Duggan Expert Rep., pp. 8, 12, 88, 93, 97, 100, 105, 116, 120, he did not specifically reference the Red Book on the particular page where he described his conclusion that Abbott's AWPs were the basis of the allowed amount in 18 to 24 percent of the paid carrier claims. Duggan Expert Rep., p. 124. That was a key example upon which Dr. Hughes relied to support his claim that Dr. Duggan's report is unreliable. Hughes Dep. Ex. 1 at 602:11-22.

[16] Abbott's experts may also have helped to overcome their lack of experience had they been able to quantifiably prove that Dr. Duggan's approach would lead to wildly disparate results as was done in the *Unum* case. Abbott's experts (the ones designated to testify) have not performed any such analysis because they were forbidden from doing so by counsel.

Respectfully Submitted,

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October 19, 2009

CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above "UNITED STATES' OPPOSITION TO ABBOTT LABORATORIES' MOTION *IN LIMINE* TO EXCLUDE CERTAIN OPINIONS PROFFERED BY PLAINTIFFS' EXPERT MARK G. DUGGAN, PH.D." to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File and Serve for posting and notification to all parties.

/s/ Mark Lavine

Dated: October 19, 2009